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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,139	03/15/2004	Paul Haefner	GUID.609PA	9243

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
02/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/801,139	HAEFNER, PAUL	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/10/2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25,35,49-53,55-62,64 and 65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,35,49-53,55-62,64 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/10/2010 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 53 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim limitation "selection of a cardiac ECG signal" is unclear because it lacks antecedent basis. It is unclear what element or elements of the system claim this limitation is meant to limit.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 25, 35, 49-53, 55, 57, 59-62, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moberg et al. (US 5,496,361, hereinafter "Moberg") in view of Mai et al. (US 6,643,548, hereinafter "Mai").

7. In regards to claims 25 and 35, Moberg discloses a patient-implantable device (Fig. 18) comprising a housing (244); a plurality of electrodes for sensing electrical activity and features (250); electrical detection circuitry (252); an accelerometer for sensing heart movements (246); cardiac acceleration sensing circuitry (248); a controller (254) configured to correlate and discriminate between normal cardiac function and arrhythmia based on the electrical and acceleration signals (col. 18, line 49 to col. 19, line 17); communications circuitry (258) to telemeter the electrical and acceleration signals (col. 19, lines 12-17); and a patient external device comprising circuitry to receive the signals (col. 19, lines 12-17). Although Moberg discloses determining arrhythmia by manipulation of the electrical and acceleration signals over time and programmability of the controller (col. 18, lines 49-67); and that the two signals

are sent to the external telemetry unit (col. 19, lines 12-16), Moberg does not expressly and explicitly disclose that the correlation is carried out by opening a correlation window based a cardiac cycle feature fiducial point of the cardiac electrical signal to correlate heart sounds with cardiac cycle features of the same heart beat over a plurality of cycles, that the implantable and external units have a memory for saving the two signals, that the external device has a user interface for providing a visual output of the two signals, or that the acceleration is an "audio" signal. However, Mai teaches opening a correlation window for cardiac cycle fiducial points and identifying heart sounds within each window (col. 9, line 39 to col. 10, line 5) to provide the predictable results of accurately determining patient condition for modification of treatment. Furthermore, it is notorious in the art to provide both implantable and external units with a memory for saving various signals to provide the predictable results of computing with ubiquitous programmable microcontrollers and allowing monitoring of patient condition over time; external telemetry devices with user interfaces for providing a visual output various signals to provide the predictable results of allowing a clinician to monitor patient condition; and monitoring heart accelerations as an "audio" signal to provide the predictable results of gathering frequencies of acceleration known to be useful in diagnosing various conditions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Moberg's invention by opening a correlation window for cardiac cycle fiducial points and identifying heart sounds within each window to provide the predictable results of accurately determining patient condition for modification of treatment; providing both implantable and external

units with a memory for saving various signals to provide the predictable results of computing with ubiquitous microcontrollers and allowing monitoring of patient condition over time; external telemetry devices with user interfaces for providing a visual output various signals to provide the predictable results of allowing a clinician to monitor patient condition; and monitoring heart accelerations as an "audio" signal to provide the predictable results of gathering frequencies of acceleration known to be useful in diagnosing various conditions.

8. In regards to claims 49, 51, 52, 59, 61, and 52, Moberg discloses diagnosing arrhythmia based on heart rate (col. 18, lines 33-34), with the acceleration signal used to confirm the diagnosis (col. 18, line 60 to col. 19, line 1). Since a high electrical-indicated rate is not confirmed as arrhythmia without acceleration signal confirmation, the system/method necessarily indicates the electrical-indicated rate as subject to "noise" (*i.e.*, not reflective of the "true" physiological rate).

9. In regards to claim 57, the sensor is on a lead (Figs. 19 and 20).

10. In regards to claims 50, 53, 55, 60, 62, and 64, Moberg discloses the essential features of the claimed invention including diagnosing arrhythmia based on heart rate (col. 18, lines 33-34), with the acceleration signal used to confirm the diagnosis (col. 18, line 60 to col. 19, line 1), but does not expressly disclose diagnosing arrhythmia based on morphology of the electrical signal, correlating the S1 sounds with the QRS complexes, or detecting heart sounds based on a human input. However, Mai teaches diagnosing arrhythmia based on morphology of the electrical signal (col. 5, line 24) to

provide the predictable results of more reliable detection of heart conditions, correlating the S1 sounds with the QRS complexes (col. 9, line 39 to col. 10, line 5) to provide the predictable results of accurately determining patient condition for modification of treatment, and detecting heart sounds based on a human input (col. 9, lines 17-25) to provide the predictable results of consistent data acquisition. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Moberg's invention by diagnosing arrhythmia based on morphology of the electrical signal to provide the predictable results of more reliable detection of heart conditions, correlating the S1 sounds with the QRS complexes to provide the predictable results of accurately determining patient condition for modification of treatment, and detecting heart sounds based on a human input to provide the predictable results of consistent data acquisition.

11. Claims 56, 58, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moberg and Mai, as applied to claims 25 and 35 above, and further in view of Lee (US 7,035,684, hereinafter "Lee"). Moberg discloses the essential features of the claimed invention except for transmitting the indication of arrhythmia to the external device or a sensor, electrodes, and housing that form a rigid unitary structure. However, Lee teaches that is it known in the art to provide indications of arrhythmia to external devices (col. 12, lines 62 to col. 13, line 3) to provide the predictable result of sending information that is most useful to the clinician; and a sensor, electrodes, and housing that form a rigid unitary structure (Fig. 3) to provide the

predictable results of an easily implantable system. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Moberg's invention by providing indications of arrhythmia to external devices to provide the predictable result of sending information that is most useful to the clinician; and a sensor, electrodes, and housing that form a rigid unitary structure to provide the predictable results of an easily implantable system.

Response to Arguments

12. Applicant's arguments filed 12/10/2010 have been fully considered but they are not persuasive. As a threshold matter, the portion of Mai relied upon for the rejection runs from column 9, line 16 to column 10, line 26. Specifically, at column 9, line 39, Mai begins to describe determining the R-wave and T-waves from the electrical signal, defining windows between these events, and determining the corresponding heart sound information over these windows. Applicant argued that the teachings of Mai are not applicable to Moberg because Mai is silent on cardiac tachyarrhythmia of the patient, and Mai teaches away from discriminating between normal cardiac function and cardiac tachyarrhythmia because Mai's time interval determination technique requires a stable cardiac rhythm and would be inapplicable where elevated and unstable cardiac rhythms are to be discriminated. The examiner's position is that (i) Moberg is relied upon for discriminating between normal function and tachyarrhythmia, and that Mai is relied upon only for the "windowing" based on electrical signals; (ii) Mai does not teach away from applying the "windowing" to tachyarrhythmia, but instead teaches providing a stable signal for heart failure analysis and is silent as to tachyarrhythmia; and (iii) the

passage at column 9, lines 16-25 describing a stable heart rate lower than a preset threshold is an alternative and not required feature of the teaching. Although the examiner agrees that the prior art must be read in its entirety, including disclosures that teach away from the claims, that examiner respectfully disagrees that the cited passage teaches that the windowing cannot be used with tachyarrhythmia patients; but instead indicates that, if one is determining the advancement of heart failure, it may be desirable to determine that an average heart rate is below a preset threshold. Furthermore, the language of this paragraph is clear that this determination is an optional alternative ("the process (optionally) advances to block 305 where the processor determines whether the heart rate is stable, for example, by determining if the averaged heart rate is lower than a preset threshold, such as 80 bpm"). Determining heart rate stability is optional ("optionally" in Mai), making this determination by calculating an average heart rate and comparing it to a threshold is optional ("for example" in Mai), and setting this threshold to be in the "sub-tachyarrhythmia" range is also optional ("such as" in Mai) ("the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004)). Lastly, it does not appear that a faster heart rate (tachyarrhythmia) would affect the operation of Mai's windowing algorithm to render it inoperable because all required signal features are still present in a tachyarrhythmic signal (*e.g.*, R-waves, T-waves, and heart sounds), albeit at a faster rate.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Primary Examiner, Art Unit 3762